REMARKS

In an office action mailed February 26, 2004, claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54 and 58-61 have been rejected under 35 U.S.C. §103, and under the judicially created doctrine of obviousness-type double patenting in view of claims 16-17 and 26-27 of U.S. Patent No. 6,395,783

In response, Applicants provide the following remarks and terminal disclaimer. Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 are pending in the application.

I. Double Patenting

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17 and 26-27 of U.S. Patent No. 6,395,783.

The Examiner has indicated that filing a Terminal Disclaimer may be used to overcome the provisional obviousness-type double patenting rejection. Therefore, a terminal disclaimer is being submitted herewith with respect to the present invention and the invention claimed in the above issued patent.

Accordingly, Applicants respectfully submit that the rejection based on the judicially created doctrine of obviousness-type double patenting has been overcome.

II. Rejection Under 35 U.S.C. §103

Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54 and 58-61 have been rejected under §103(a) as being unpatentable over U.S. Patent No. 5,189,064 to Blum et al., and U.S. Patent

No. 3,639,607 to Phillips, in view of U.S. Patent No. 5,332,736 to Carmosin et al.

All of the cited documents were disclosed in an information disclosure statement filed by Applicants.

According to the Examiner, Blum discloses that GABA and GABA agonists are useful broadly in methods for the treatment of addiction or abuse of drugs such as cocaine and alcohol (i.e. reducing seizure activity during alcohol withdrawal) since GABA and GABA agonists increase GABA levels in a mammal.

The Examiner cites Phillips for allegedly disclosing that anticonvulsants are known to be useful broadly in methods of treatment of tobacco addiction.

The Examiner recognizes that neither Blum nor Phillips expressly disclose using the particular compound disclosed, i.e. topiramate, in the present application or their effective amounts in methods of treating addiction-related behavior.

Carmosin has been cited by the Examiner for disclosing that "topiramate is an anticonvulsant which is a known GABA agonist." Therefore, in view of Blum and Philips, the Examiner contends that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ topiramate in methods of treating addiction-related behavior. Applicants respectfully disagree.

Firstly, Applicants fail to appreciate where Carmosin states that topiramate is a GABA agonist. Regardless, the genus "GABA agonist" is a broad genus containing numerous compounds that act in a variety of ways, producing a variety of resulting effects. The same is true for the genus "anticonvulsant."

Within the genus "GABA agonist" there is another variable due to the fact that there is more than one GABA receptor. For example, a GABA-a and GABA-b receptor have been identified - each affecting different pathways. Different compounds act on different GABA receptors.

It is clear from the literature that topiramate is not a simple GABA agonist. Topiramate does not bind at either the GABA or the benzodiazepine binding sites of the GABA-a receptor. Topiramate is structurally unrelated to other anticonvulsants and to GABA.

Preclinical data suggests that topiramate's anticonvulsant activity is promoted by several mechanisms including modification of sodium and calcium dependent action potentials, as well as by modifying the conductance at the kianate sensitive glutamate receptors.

All anticonvulsants do not block addictive drug induced phasic elevations of dopamine in the brain.

Similarly, not all GABA agonists are effective at treating drug addiction. In fact, well known GABA agonists such as phenobarbital and benzodiazepines have no claims for efficacy in the treatment of drug abuse - they are themselves drugs of abuse.

Despite the anecdotal reports used to support the claims in the Phillips patent, in more than thirty (30) years since the patent was granted, anticonvulsants *per se* have never been shown to be effective in the treatment of nicotine addiction or any other addiction to drugs of abuse.

Accordingly, Applicants contend that one of ordinary skill in the art would not have reasonably expected that topiramate would have the same therapeutic usefulness in methods of treating addiction related behavior of a mammal, as the compounds disclosed in Blum or Phillips.

As a result of Applicants invention, it was discovered that topiramate is effective at treating addiction-related behavior of a mammal. One of ordinary skill would need to conduct countless experiments with all of the anticonvulsants disclosed in Carmosin and Phillips, and all of the GABA agonists disclosed in Blum, to find compounds effective for treating addiction-related behavior.

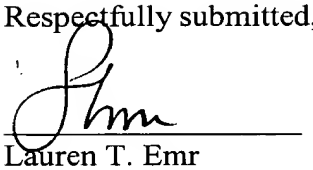
Applicants respectfully submit that the skilled artisan would not arrive at the claimed invention from reading Blum and Phillips in view of Carmosin.

Carmosin merely adds that topiramate is an anticonvulsant. Carmosin discloses hundreds of compounds that may have anticonvulsant activity. Carmosin does not disclose or suggest that any of the anticonvulsants are suitable for treating addiction related behavior of a mammal.

Since neither Blum or Phillips disclose or suggest using topiramate to treat addiction related behavior, and Carmosin merely adds that topiramate is an anticonvulsant, Applicants respectfully submit that the claimed invention is not obvious in view of the cited documents.

In light of the foregoing amendments and remarks, Applicants' respectfully submit that the application is now in condition for allowance. If the Examiner believes a telephone discussion with Applicant's representative would be of assistance, he is invited to contact the undersigned at his convenience.

Respectfully submitted,



Lauren T. Emr
Attorney for Applicant
Reg. No. 46,139

Hoffmann & Baron LLP
6900 Jericho Turnpike
Suite 200
Syosset, NY 11791
Tel: (516) 822-3550
Fax: (516) 822-3582